Recent Advances in **Interventional Guidewires**

Complex PCI, CTOs are driving demand for new types of guidewires

By Dave Fornell

Guidewire engineering has become more advanced over the past decade as interventional cardiologists have advanced their trade to tackle much more complex lesions, including chronic total occlusions (CTO). Operators have moved beyond simple, straightforward percutaneous coronary intervention (PCI) lesions and are now tackling harder-to-reach lesions. These lesions are often located in tortuous vessel anatomy and include revascularizing completely blocked CTO vessel segments. CTOs often require guidewires approaching the blockage both antegrade and retrograde, and at times using a subintimal approach. These procedures often require several types of guidewires and frequent exchanges, so these procedures have become the biggest growth area for new guidewire technology.

Choosing the Right Guidewire for CTO Procedures

These more complex lesions require a tool box of guidewires that have varying attributes to address specific access issues. However, there are many dedicated CTO guidewires on the market — too many for a single operator to become proficient with, explained Bill Lombardi, M.D., director of complex coronary artery interventions at the University of Washington, Seattle, and a top expert in CTOs. He said it is easy to get into "paralysis by analysis," where there are just too many choices, information overload and confusion about what to pick. He said the idea of the hybrid CTO approach is getting rid of extraneous equipment in the lab and just keeping a handful of tools the operator can master.

"It can get confusing," agreed Khaldoon Alaswad, M.D., a CTO expert and director of the cardiac catheterization lab at Henry Ford Hospital, Detroit. "We like to limit the number of devices used per procedure, not only from an economic standpoint, but also from an efficiency standpoint."

In his lab, he said they try to pick a limited number of wires that all the staff can become experts in using and have application across the department for different types of procedures. "With antegrade wire escalation you go from a soft tip polymer jacketed Fielder XT-A, XT or XT-R, to a pilot 200 and Confianza, and we have added harder tipped wires like the Hornet 14, Astato 20 and Astato 40. For retrograde access we use most of the micro catheters available, including the Mamba, Corsair, FineCross and Micro 14. Each one of us has their own workhorse wires and guide catheters we use. If you have a limited number of tools, devices and wires, you learn to master them," Alaswad said.

"There are a lot of me-too devices out there, so don't get lost in that, just focus on picking very different devices, but keep the number limited. Less choices is actually better," Lombardi explained.

Lombardi said most CTO operators pick just three types of wires to concentrate on:

- Stiff polymer jacketed wire. An example would be the Pilot 200 (Abbott);
- A stiff penetrating wire, like a Confianza Pro 12 (Asahi) or a Hornet 14 (Boston Scientific); and
- A more steerable guide wire, like a Gaia series (Asahi), if the operator knows where they are going inside the vessel.

"In general, we follow the

Participants

Abbott
www.cardiovascular.abbott

Bard
www.crbard.com

Boston Scientific
www.bostonscientific.com/content/gwc/en-US/products/guidewires.html

Teleflex
www.teleflex.com/usa/product-areas/interventional/coronary-interventions/guidewires/

Terumo
www.terumois.com

Scranton Gillette Communications obtained the model specifications from the manufacturers.

hybrid algorithm, where we try not to spend too much time on one particular method of crossing if it is not working," said Kevin Rogers, M.D., CTO expert and director of vascular medicine at the University of Colorado Hospital. "With wire escalation, the Pilot 200 is really our workhorse crossing wire. I Think Fielder XT is good if we need to go subintimal with a plan to re-enter the lumen, or if there is a micro channel. For septal crossing, Asahi Sion is what we go to first, but then Fielder XT. We typically go to a Confianza Pro 12 as our last-resort wire. It's good to have five wires you are really comfortable with and try to stay away from the really aggressive wires early on, especially if the anatomy is ambiguous at all."

Basic Guidewire Characteristics

There are dozens of types of guidewires on the market with different performance characteristics designed to navigate the wire through vessels to reach a target lesion or vessel segment. Once the tip of the device arrives at its destination, it acts as a guide that larger catheters can rapidly follow for easier delivery of stents or balloons to treat the vessel.

Wires are characterized by their pushability, steerability, torque and opacity. Pushability is the amount of force needed to advance the wire. Steerability is the ability and responsiveness of the wire tip to navigate vessels. Torque is the response of the wire to turning by the operator when navigating vessels. Its opacity is its level of visibility under fluoroscopic X-ray angiography imaging.

Guidewires come in two basic configurations: solid steel or nitinol core wires, and solid core wire wrapped in a smaller wire coil or braid. Coiled or braided wires offer a large amount of flexibility, pushability and kink resistance. Some of Boston Scientific's guidewires use a nitinol tube with micro-cut slots instead of braided wire to improve torque control.

Nitinol wire, used by itself or braided with stainless steel, helps increase flexibility and allows the wire to spring back into shape after navigating a tortuous vessel segment. Many guidewires have a floppy tip and a stiff body to enable easy tip navigation, with good pushability offered by the stiffer section of the wire.

Some wires are coated with a polymer, such as silicone or polytetrafluoroethylene (PTFE), to increase lubricity. Hydrophilic coatings reduce friction during deployment and make for easier movement in tortuous vessels.

Nitinol Safety Concerns Raised by FDA

In April 2019, the FDA published a draft guidance titled, "Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol," which includes proposed recommendations on what manufacturers should include in their premarket submission of a device containing nitinol. Nitinol is an alloy of nickel and titanium that is commonly used in guide wires, stents and other medical devices. The recommendations include testing to evaluate susceptibility to corrosion, biocompatibility and performance under certain conditions of stress/strain or temperature, labeling — including language about the risk of potential allergic reactions to the metals — information on how the device is manufactured and other factors that could affect the breakdown of the material in the body.

There are always a lot of guidewires used in CTO cases, but they all look the same so it can be confusing as to which is which as they are exchanged out and are all set on the same table. John Messenger, M.D., at the University of Colorado, likes to write the name of each wire on a towl and put the towel on top to keep them straight for himself and staff in the room.

Earlier this year, the FDA announced a broad effort to engage the public, scientists and industry stakeholders to gather information about medical device materials. The goal of the effort is to ensure the current state of the science is reflected in agency decision-making, to identify any critical gaps in the existing science that need to be addressed, and to determine what approaches should be considered to further understanding of the materials and improve the safety of devices for patients.

"The materials used in devices are important, both to the function of the device and to the safety of the device because of how the human body may respond to the materials used. That's why we've committed to taking steps to advance the science underlying the effects of specific materials, including nitinol, to inform our evaluation of devices and support the development of screening tools to assess potential health risks to individual patients," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "Nitinol has unique properties that have led to an increase in its use in devices – particularly for orthopedic fracture fixation, cardiovascular stents, guidewires and other devices used in minimally-invasive medical procedures. Devices made with nitinol provide many important benefits to patients, but we need to be able to assess whether, among other things, there are any health risks when the material comes into contact with various parts of the body for extended periods of time." DAIC

Comparison Chart Compiled by Diagnostic and Interventional Cardiology

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COMPARISON CHART

Guidewires

Additional submitted information appears on our website at www.DIcardiology.com.

Company	Abbott				Bard	Boston Scientific						
Product name	Hi-Torque Balance Middleweight	Hi-Torque Balance Middleweight Universal	Hi-Torque Whisper	Hi-Torque All Star	Porter	Thruway	Amplatz Super Stiff Guidewire	Meier	Magic Torque	Magic Torque DLVR	Savion FLX	Savion DLVR
FDA / CE mark year cleared	FDA 2010	FDA 2008	FDA 2003	N/S	2006	FDA 2003	FDA 1994	FDA 2002	FDA 1994	FDA 2018	FDA 2018	FDA 2018
Indicated anatomy	All Hi-Torque guidewires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA)				Peripheral and coronary	Intended for general intravascular use in the peripheral vasculature						
Categorize usage	Frontline use	Frontline use	N/S	Extra support use	Crossing, hydrophilic, CTO	Extra support	Extra support	Extra support	Support	Workhorse 0.035 wire with superior rail support	Workhorse/ frontline 0.014 wire	Extra support - device delivery support
Core type	N/S	N/S	N/S	N/S	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed
Diameters (inch)	0.014	0.014	0.014	0.014	0.014	0.014, 0.018	0.035, 0.038	0.035, 0.038	0.035	0.035	0.014	0.014
Lengths available (cm)	190, 300	190, 300	190, 300	190, 300	195, 300	130, 190, 300	130, 190, 300	185, 260, 300	180, 260	315	185, 300	182, 300
Tip shapes (straight, angled, J-tip, etc.)	Straight	Straight	Straight	Straight	Straight	J-tip, straight, short, long and extra long taper	J-tip, straight, short, long and extra long taper	J-tip, C-tip	Straight (shapeable)	Straight (shapeable)	Straight (shapeable), angled	Straight (shapeable), angled
Tip flexibility/ stiffness (Choose one: floppy, intermediate or standard)	N/S	N/S	N/S	N/S	Various (3, 6, 9, 12 g tip stiffness)	Floppy	Variable	Intermediate	Intermediate	Intermediate	Floppy	Floppy
Tip load, expressed in grams of force needed to bend (e.g. 12 g, 3 g, etc.)	0.6	0.7	1	0.7	3, 6, 9, 12	1.3, 1.7, 2, 4	N/A	N/A	N/A	N/A	2.9	0.8
Support level (choose one: light/floppy, moderate, extra support or super support)	Moderate support	N/S	N/S	Extra support	N/S	Extra support	Super, extra support	Super	Moderate	Moderate	Moderate	Maximum
Coating (specify hydrophilic, hydrophobic, etc.)	Hydrophilic or hydrophobic	Hydrophilic	Hydrophilic	Hydrophobic	Hydrophilic	Non-hydrophilic (silicone)	PTFE, PTFE/ heparin	None	Hydrophilic/ distal 10 cm	Exclusive Glidex hydrophilic/ distal 10 cm, PTFE coating	ICE hydrophilic coated polymer sleeve	ICE hydrophilic coated, distal 3 cm is uncoated
Core material	Elastinite nitinol	Elastinite nitinol	Durasteel stainless steel	Stainless steel	Stainless steel	Stainless steel	Stainless steel	Stainless steel	Stainless steel	Stainless steel	Proximal - stainless steel distal - linear elastic nitinol	Stainless steel
Wire outer coils and coverings (centimeters)	N/S	N/S	N/S	N/S	3 cm platinum alloy spring coil	N/S	N/S	N/S	N/S	N/S	Polymer sleeve tip	3 cm spring coil tip
Tip style	Shaping ribbon	Shaping ribbon	Core to tip	Core to tip	Core to tip	Spring coil	Spring coil	Spring coil	Spring coil	Spring coil	Polymer sleeve nitinol tip, 2 cm shape ribbon	Spring coil
Sleeve: yes/no, and material	None	Yes, intermediate polymer cover	Yes, full polymer cover	Yes, intermediate polymer sleeve	N/S	No	No	N/S	No	No	Yes, polymer	No

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N/A = Not applicable
N/S = Not specified

	Boston Scientific		Teleflex					Terumo					
	Platinum Plus	Zipwire Hydrophilic Guidewire	R350 Guidewire	Raider Guidewire	Bandit Guidewire	Warrior Guidewire	Spectre Guidewire	Glidewire	Glidewire Advantage	Glidewire GT	Glidewire Gold	Runthrough NS Hypercoat	Runthrough NS Extra Floppy
	FDA 1995	FDA 2006	FDA 2015, CE mark 2017	FDA 2017	FDA 2018	FDA 2018	FDA 2017	1986 (80 - 260 cm); 2015 (350 - 450 cm)	2007 (0.018 - 0.038); 2013 (0.014)	1996 (0.018); 2017 (0.016)	1996	2007	2007
	Intended for general intravascular use in the peripheral vasculature		Coronary and peripheral	Coronary and peripheral	Coronary and peripheral	Coronary and peripheral	Coronary and peripheral	Peripheral, visceral	Peripheral, visceral	Visceral	Peripheral	Coronary, peripheral	Coronary, peripheral
	Support	Resistant lesions - hydrophilic	Externalization	Resistant lesions	Frontline navigation, resistant lesions	Challenging occlusions	Workhorse	Diagnostic, navigation, workhorse, lesion crossing	Diag, navig, workhorse, crossing, delivery	Diagnostic, navigation	Workhorse, lesion crossing	Specialty, navigation, crossing, delivery	Workhorse, navigation, crossing, delivery
	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed
	0.014, 0.018, 0.025	0.018, 0.025, 0.035, 0.038	0.013	Tip: 0.014, shaft: 0.014	Tip: 0.008, shaft: 0.014	Tip: 0.009, shaft: 0.014	Tip: 0.014, shaft 0.014	0.018, 0.025, 0.032, 0.035, 0.038	0.014, 0.018, 0.035	0.016, 0.018	0.018	0.014	0.014
	60, 145, 180, 260	80, 150, 180, 260	350	200, 300	200, 300	200, 300	190, 300	80, 120, 150, 180, 260, 350, 400, 450	180, 260 (0.035); 180, 300 (0.014 and 0.018)	180	180, 300	180, 300	180, 300
	Straight; long and short taper	Straight, angled, J-tip, long taper	Straight, shapeable	Straight, shapeable	Straight, shapeable	Straight, shapeable	Straight, shapeable	Angled, straight, J-Tip, shapeable, bolia double-angle	Angled	Straight shapeable (0.016, 0.018), double-angle (0.016, 0.018), 45 degrees (0.018), 90 degrees (0.018)	45 degree angle, 70 degree angle	Straight shapeable	Straight shapeable
	Intermediate	Variable	N/S	N/S	N/S	N/S	N/S	Floppy, intermediate, standard	Intermediate, standard	Floppy	Intermediate	Floppy	Floppy
	4, 5, 7	N/A	3	4	0.8	14	0.9	N/S	GWA 035 - 11.1; GWA 018 - 2.5; GWA 014 - 2.1	N/S	3 cm 45 degree angle - 4.1	1	0.6
	Extra support	Moderate	N/S	N/S	N/S	N/S	N/S	Moderate/Extra	Extra	Moderate	Moderate	Moderate	Moderate
	Hydrophilic/ distal 11 cm	Hydrophilic	200 cm distal hydrophilic	30 cm distal hydrophilic	17 cm distal hydrophilic	20 cm distal hydrophilic	42 cm distal hydrophilic	Terumo Glide hydrophilic coating	25 cm hydrophilic coating distal, PTFE coating proximal	Terumo Glide hydrophilic coating	Terumo Glide hydrophilic coating	25 cm hydrophilic (Enhanced M coat)	24.8 cm hydrophilic, 2 mm hydrophobic tip (silicone)
	Stainless steel	Nitinol	Nitinol	Stainless steel	Stainless steel	Stainless steel	Stainless steel to nitinol	Nitinol	Nitinol	Nitinol	Nitinol	Hybrid - stainless steel proximal, nitinol distal tip	Hybrid - stainless steel proximal, nitinol distal tip
	N/S	N/S	5 cm spring coil	25 cm spring coil w/ 30 cm polymer jacket	16 cm spring coil w/ 17 cm polymer jacket	20 cm spring coil	25 cm spring coil	N/A	N/A	N/A	N/A	3 cm platinum coil, 22 cm stainless steel coil	
	Spring coil	Polymer sleeve	Core-to-tip	Core-to-tip	Core-to-tip	Core-to-tip	Core-to-tip	Core to tip	Core to tip	Core to tip	Core to tip	Core to tip	Core to tip
	No	Yes, polymer	No	Yes, polymer	Yes, polymer	No	No	N/A	N/A	N/A	N/A	N/A	N/A